## AFFIDAVIT OF VOLUNTARY SURRENDER OF PHARMACY PERMIT

STATE OF <u>California</u> )	
STATE OF <u>California</u> ) ss. COUNTY OF <u>Ovande</u> )	
I, Glen Olsheim	, being first duly sworn upon my oath state:
1. I am the Chief Oferat	of California Pharmacy and
Compounding Center, Inc., 400 Birch Street	, Ste 120, Newport Beach, CA 92660, a pharmacy
licensed by the Missouri Board of Pharmacy	as permit number 2010002058.

- 2. I understand that the Missouri Board of Pharmacy is authorized to pursue disciplinary action upon permit number 2010002058, and that the Missouri Board of Pharmacy is not required to accept a voluntary surrender of this permit.
- 3. It the pharmacy's intent and desire at this time, after due deliberation, to voluntarily surrender its pharmacy permit, number 2010002058, to the Missouri Board of Pharmacy and to provide that Board with any other documents or certificates in its possession evidencing the existence of said Missouri pharmacy permit.
- 4. I further understand and agree that if California Pharmacy and Compounding Center, Inc., applies for licensure in the State of Missouri following the execution of this Affidavit, all facts and information gathered prior to execution of this affidavit by the Missouri Board of Pharmacy concerning any possible or alleged violations of Chapter 338, RSMo, may be considered in the Board's decision of whether to grant a new license or permit along with the following violations to which California Pharmacy and Compounding Center, Inc. stipulates:

- A. On or about August 29, 2016, Respondent self-reported to the Board disciplinary action taken by the California Board of Pharmacy ("California Board") pursuant to its Decision and Order effective September 9, 2016 (the "California Order").
- B. The California Order adopts a Stipulated Settlement and Disciplinary Order entered into between Respondent and the California Board which arises out of a Second Amended Accusation filed against Respondent by the California Board.
- C. Respondent agreed that the California Board could establish a factual basis for the charges contained in the Second Amended Accusation and gave up its right to contest them.
- D. Respondent's California license is revoked, but the revocation is stayed and Respondent's California license is placed on probation for four (4) years.
- E. The Second Amended Accusation contains eleven (11) causes to discipline Respondent, as follows:
  - i. Failing to ensure the security, integrity and/or authority of a patient's prescription by failing to verify it with the prescribing physician.
  - ii. Compounding and/or dispensing prescriptions for Releana, an oral form of human chorionic gonadotropin, containing significant errors, omissions, irregularities and/or uncertainties.
  - iii. Compounding and selling Releana to an entity not licensed by the California Board as a pharmacy or wholesaler in California.
  - iv. Selling, delivering, transferring, holding, or offering for sale drugs that Respondent knew or should reasonably have known were misbranded.

- v. Dispensing Releana with prescription labels that did not state the concentration or strength of the active ingredient.
- vi. Aiding and abetting an entity not licensed by the California Board as a pharmacy or wholesaler in California to sell Releana to physicians.
- vii. Failing to maintain a written policy and procedure manual that included the procedures for maintaining, storing, calibrating, cleaning, and disinfecting the autoclave and convection oven used in compounding.
- viii. Assigning erroneous expiration dates to a prescription which exceeded the shortest expiration date of any component of the compounded product.
- ix. Failing to report an adverse event regarding a patient to the California Board within twelve (12) hours.
- x. Assigning a beyond use date of one year to compounded oxytocin without adequate supporting stability studies to justify the beyond use date assigned.
- xi. Failing to conduct and document end-product testing of 49 batches of Trimix, an injectable compounded product consisting of three active ingredients used to treat erectile dysfunction, for sterility and pyrogens and failing to quarantine until the end-product testing confirmed sterility and acceptable levels of pyrogens.
- F. Respondent also self-reported disciplinary taken by the Colorado State Board of Pharmacy (the "Colorado Board") by way of correspondence to the Board dated March 30, 2017.

- G. Respondent entered into a Stipulation and Final Agency Order with the Colorado Board (the "Colorado Order") based on the California Order. Respondent signed the Colorado Order on February 17, 2017,
- H. Respondent agreed to relinquish and cancel its Colorado license which has the force and effect of a revocation order.

## Cause to Discipline in Missouri

- l. Cause exists for Petitioner to take disciplinary action against Respondent's permit in Missouri under §338.055.2(5), (8), (13) and (15), RSMo, which state in pertinent parts:
  - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
    - (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

\* \* \*

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, include, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state:

\* \* \*

(13) Violation of any professional trust or confidence;

- (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.
- J. Cause to discipline Respondent exists under §338.055.2(5), RSMo, in that Respondent's conduct forming the basis for the California Order and the Colorado Order constitutes incompetency, misconduct, gross negligence, dishonesty, fraud and/or misrepresentation in the performance of Respondent's functions or duties as a licensed pharmacy.
- K. Cause exists to discipline Respondent exists under § 338.055.2(8), RSMo, in that the aforementioned disciplinary action in California and Colorado is grounds for which discipline is authorized Missouri.
- L. Cause to discipline Respondent exists under §338.055.2(13), RSMo in that the conduct forming the basis for the California Order and the Colorado Order constitutes a violation of professional trust and confidence.
- M. Cause to discipline Respondent exists under §338.055.2(15), RSMo, in that aforementioned conduct forming the basis for the California Order and the Colorado Order constitutes a violation of the drug laws or rules and regulations of this state, the State of California, the State of Colorado, and/or the federal government.
- 5. I fully understand that, by my execution of this Affidavit, California Pharmacy and Compounding Center, Inc., shall surrender and lose any rights under the law to operate as a pharmacy in the State of Missouri and will not be able to again operate as a pharmacy until a new Missouri pharmacy permit application is submitted to and approved by the Board.
- 6. I further understand that the abovementioned pharmacy permit will not be returned by the Missouri Board of Pharmacy and that such permit will cease to exist when it is surrendered.

- 7. I acknowledge and affirm by this sworn statement that no threats, promises, or assurances of any kind have been made regarding the voluntary surrender of the permit except as noted above, nor have I been threatened or coerced to so act in any way, but rather California Pharmacy and Compounding Center, Inc., does hereby voluntarily surrender its Missouri pharmacy permit by and with this Affidavit.
- 8. I acknowledge and affirm that I understand that the Board of Pharmacy will maintain this Affidavit of Voluntary Surrender as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

Date: 11/28/2017

CALIFORNIA PHARMACY AND COMPOUNDING CENTER, INC.

By:

Glen Olsheim

(printed)

Oferating Officer

Subscribed and sworn to before me this 28 day of December, 2017.

LINDA L. COURTER Commission # 2113307 Notary Public - California **Orange County** My Comm. Expires Jun 24, 2019

My Commission Expires: June 24, 2019

(Print, type or stamp name of notary

ROBERT J. BRUNDAGE EDWARD C. CLAUSEN MARK W. COMLEY KIMBERLY J.Z. GUTHRIE JOSHUA L. HILL



CATHLEEN A. MARTIN RYAN J. MCDANIELS STEPHEN G. NEWMAN JOHN A. RUTH ALICIA EMBLEY TURNER

December 18, 2017

Ms. Kim Grinston Missouri Board of Pharmacy P.O. Box 625 Jefferson City, MO 65102

Re:

Missouri Board of Pharmacy v. California Pharmacy and Compounding Center, Inc.

Permit No. 2010002058

Dear Kim:

Enclosed please find California Pharmacy and Compounding Center, Inc.'s fully executed Affidavit of Voluntary Surrender of Pharmacy Permit. It matches the version sent by my office. California Pharmacy and Compounding Center, Inc. was not represented by an attorney.

Please let me know if you have any questions or concerns.

Sincerely,

NEWMAN, COMLEY & RUTH P.C.

By:

Alicia Embley—Turner turnera@ncrpc.com

AET:kjh Enclosure